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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,691	06/26/2001	John Bondo Hansen	6034.200-US	1796
7590	12/30/2003		EXAMINER	JIANG, SHAOJIA A
Reza Green, Esq. Novo Nordisk of North America, Inc. Suite 6400 405 Lexington Avenue New York, NY 10174-6401			ART UNIT	PAPER NUMBER 1617
DATE MAILED: 12/30/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/891,691	HANSEN ET AL.
	Examiner Shaojia A Jiang	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 September 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-12, 19-24, 26 and 27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12, 19-24, and 26-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ . 6) Other: \_\_\_\_\_ .

## **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on September 22, 2003 in Paper No. 17 wherein claims 13-18 and 25 are cancelled and claims 1-12, 19-24, and 26-27 have been amended.

Currently, claims 1-12, 19-24, and 26-27 are pending in this application.

The following is a new rejection necessitated by Applicant's amendment filed on September 22, 2003 in Paper No. 17.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 19-24, and 26-27 as amended now by adding "snacking" are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation "fat-containing food" and the claim also recites "snacking" which is the narrower statement of the range/limitation since one of ordinary skill in the art would interpret that "fat-containing food" encompasses "snacking". It is noted that the instant specification also discloses that "fat food, such as e.g. snacking" (see page 3 lines 30-31).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 19-24, and 26-27 as amended now by adding "snacking" are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 5889002, WO 9726265, and WO 9903861, of record) in view of the Merck Manual of

Diagnosis and Therapy (17<sup>th</sup> ED) (see pages 59-61, of record) for the same reasons of record stated in the Office Action dated May 20, 2003.

Nielsen et al. (US 5889002) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species (see abstract, col.1 lines 21-22, 45-50, col.2 lines 29 to col.7) are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart diseases, coronary heart diseases (see col.13 lines 19-24), and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes (see col.13 line 62 to col.14 lines 8). Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See col. 18 lines 53-55.

Nielsen et al. (WO 9726265) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart diseases (see abstract, page 1 lines 11, 16, 26-27, and 32-33, page 3-10 and page 52 claim 25) and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes (see page 20 lines 9-16). Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See page 27 lines 18-20.

Nielsen et al. (WO 9903861) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are

potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease (see abstract, page 1 lines 8, 26 and 32-33, page 3-13 and page 52 claim 25) and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes (see page 20 lines 10-18).. Nielsen et al. also teaches that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. See page 2 lines 30 to page 3 line 3. Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See page 30 lines 4-6.

Nielsen et al. does not expressly disclose a method for reducing the consumption of fat-containing food and snacking employing the active compounds of Nielsen et al., represented by the general formula I therein. Nielsen et al. does not expressly disclose the instant fat-containing food contains at least 10 kcal% fat.

The Merck Manual of Diagnosis and Therapy (16<sup>th</sup> ED) teaches that that a large amount of fat-containing food to be consumed or a large fat intake is tightly associated with obesity (see 4<sup>th</sup> paragraph of the right column at page 59), and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease. See the right column of page 61.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food and snacking, and to employ food herein containing from 10-45 kcal% fat.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food and snacking, since the active compounds of Nielsen, potassium channel openers, are known to be useful in methods of treating hypertension, heart disease, and especially obesity hyperinsulinemia, insulin resistance and diabetes. Moreover, a large amount of fat-containing food to be consumed or a large fat intake is well known to be tightly associated with obesity, and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease according to Merck Manual. Therefore, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutic effect in treating obesity and its complications by reducing the consumption of fat-containing food which may contain at least 10 kcal% fat.

Hence, the disclosures of Nielsen et al. have clearly provided the motivation for the instant invention. Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Applicant's remarks filed September 22, 2003 in Paper No. 17 with respect to this rejection of claims 1-12, 19-24, and 26-27 made under 35 U.S.C. 103(a) of record stated in the previous Office Action May 20, 2003 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior

art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, Applicant's arguments that "Obesity has a number of causes", and Nielsen et al. only suggests the use of potassium channel openers" and "No indication is given in Nielsen that the potassium channel openers can be used treat other causes of obesity", are unconvincing. It is noted that the instant specification also discloses that "the present invention provides the use of the potassium channel openers....." (emphasis added, see page 3 lines 30-31). As discussed above, a large amount of fat-containing food to be consumed or a large fat intake is well known to be tightly associated with obesity, and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease according to Merck Manual. Therefore, one of ordinary skill in the art would have reasonably expected that the same potassium channel openers of Nielsen would have beneficially therapeutic effect in treating obesity and its complications by reducing the consumption of fat-containing food.

Moreover, as discussed in the previous Office Action, it is noted that Applicant admits herein that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake since Applicant employs an obese Zucker rat as the testing model for the instant claimed method. See page 23 lines 1-15 in the specification. Thus, Applicant clearly acknowledges that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake as discussed by the examiner above.

Therefore, Applicant's own admission supports the examiner's position for the motivation for the instant invention.

Applicant's testing results in the specification at page 23 lines 1-15 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive since the results on the employment of the particular compound on obese rates show expected therapeutic effects as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Further, testing herein merely demonstrate a single particular compound within the broad genus of the instant claims. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the actives in the claimed method herein. See MPEP § 716.02(d).

Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

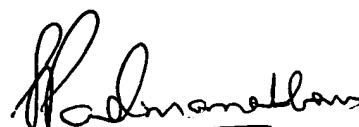
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
December 17, 2003

  
SREENIVASAN PADMANABHAN  
SUPERVISORY PATENT EXAMINER

12/29/03